



Atty. Dkt. No. 067286-0276

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: James C. KENNEDY et al.

Title: PHOTOCHEMOTHERAPEUTIC METHOD USING 5-AMINO  
LEVULINIC ACID AND PRECURSORS THEREOF

Appl. No.: 10/605,824

Filing Date: 10/29/2003

Examiner: S. Sharareh

Art Unit: 1617

**RESPONSE TO RESTRICTION REQUIREMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the restriction requirement set forth in the Office Action mailed October 20, 2004, Applicants hereby provisionally elect Group II, Claims 8-20, for examination, with traverse.

The examiner has required restriction to one of the following groups:

Group I Claims 1-7, 14-18 in part, drawn to methods of treating a non-malignant lesion of the esophagus in a patient with effective amounts of a precursor of protoporphyrin IX, classified in class 424, subclass 9.6; and

Group II Claims 8-20 in part, drawn to methods of treating non-malignant lesions of esophagus in patients with an agent which is not a photosensitizer but induces the synthesis of protoporphyrin IX in vivo, classified in class 514, subclass 561.

The examiner argues that claims 1-20 are generic to patentably distinct species. Specifically, the patentably distinct species in the examiner's view are (a) a specific precursor

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of protoporphyrin IX and (b) a specific agent which is not a photosensitizer but induces the synthesis of protoporphyrin IX *in vivo*. Applicant respectfully disagrees.

All claims in an application must be examined, notwithstanding patentably distinct inventions, if the search and examination can be made without “serious burden.” MPEP § 803 (emphasis added). The examiner attempts to establish a “serious burden” by showing that the species identified would be classified differently. However, the groups identified generally have a genus-subgenus relationship. In other words, a specific precursor of protoporphyrin IX is generally a sub-genus of a specific agent which is not a photosensitizer but induces the synthesis of protoporphyrin IX *in vivo*. Thus, the examiner will have only minimal additional burden to search and examine Group I when searching and examining Group II. Such a burden is not considered “serious.”

In addition, the classification is incorrect. The examiner classifies Group II in a class and subclass limited to chemical compounds with specific structural features. However, these structural features are not claimed nor are they inherent in a specific agent which is not a photosensitizer but induces the synthesis of protoporphyrin IX *in vivo*. On the other hand, Group I is classified in a subclass entitled “Diagnostic or test agent produces *in vivo* fluorescence.” This subclass would be appropriate for both Groups I and II. Thus, the articulation of separate classifications is inaccurate, and accordingly, it does not establish undue burden.

Furthermore, the Examiner relies on the U.S. Patent classification for making the present restriction requirement. It is respectfully submitted that the U.S. Patent Classification system is not rooted in any scientific principles, rather, the U.S. Patent classification system is merely a means for organizing the subject matter of various patent applications and grouping different applications into various categories. Thus, merely asserting that the claimed invention falls under different classifications according to the U.S. Patent Classification system and hence acknowledges their differences constitutes improper grounds for restriction.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the restriction requirement.

For the election of species, Applicants elect 5-aminolevulinic acid with traverse. Applicants understand that should the elected species be found allowable, that the Examiner will follow the procedures of MPEP 803.02 and expand the search.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application is respectfully requested.


The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16 1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date June 21, 2005

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